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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,233	08/02/2003	Matthias Boldt	17836	2446

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,233	BOLDT, MATTHIAS	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/27/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/27/2007 has been entered.

Claim Objections

Persuant to 37 CFR 1.126, misnumbered original claims 2-34 were renumbered as claims 1-33. Accordingly, misnumbered claims 2-40, as amended (7/27/2007), have been renumbered as claims 1-39. The Examiner requests that the Applicant use the correct numbering and appropriate status modifiers in the next reply. The rejections below will refer to the claims as renumbered, i.e. claims 1-39.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. The Applicant amends the claims 26-33 to include divided doses, however, in each of the components the divided dose was calculated in the Specification based on a total daily dose range divided into four doses (Specification, paragraphs 0017,0019,0021,0023,0025,0027). The amendment includes less than four divided doses and more than four divided doses, none of which, relative to the claimed divided dose range, were within the possession of the inventors at the time the invention was filed. The Applicant presents new claims 32-39 directed to a method of weight control in which a vinca alkaloid in combination with one or more of the listed compounds or one or more compounds that increase cyclic AMP or exert an action similar to cAMP in a mammal. However, there is no disclosure in the Specification and claims as original filed which support these claims. The Specification indicates that the method disclosed herein comprises administration of a compound comprising caffeine, an adrenergic amine, forskolin, guggulsterone, an alpha-2-receptor antagonist and a vinca alkaloid (Paragraph 0010). The only variation permissible with respect to the above components is that addition of black pepper extract, amounts of the components, and substitution of an analogous compound having a similar function for one of the compounds listed Paragraph 0029 (See Paragraphs 0011, 0029, 0030). As such, there is nothing in the disclosure that establishes that the inventors contemplated a weight control method that contains less than the components indicated above.

Claims 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-33 are dependent on claim 26, method of use claim. However, claims 27-33 are directed to composition claims and refer to claim 26 as a composition claim. As such, the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinery (US Pat. App. Pub. 2004/0077556) in view of Lawn et al. (US Pat. 6,821,774), Brink (US Pat. 6,113,949), Majeed et al. (US Pat. 5,804,596) and Marev.

Chinery discloses a composition containing caffeine (which increases cAMP), at least one of synephrine (which increases cAMP), hordenine, octopamine, tyramine and N-methyltyramine, yohimbine (which increases cAMP), which promotes weight loss in mammals (paragraphs 0075-0076, 0090-0095, 0103-0105,0155-0157). It is disclosed that the composition may be administered orally and can be in the form of capsules or powder or a liquid suspension, colloidal suspension, shake or aqueous mixture, which can be taken once daily, or in divided doses taken, for example, before the morning exercise session and after said exercise in the mid-afternoon (Paragraphs 0175-0177). It is disclosed that the amount of caffeine is most preferably approximately 150 mg to 500 mg per day, the amount of synephrine is most preferably approximately 40 mg to 80 mg per day and that the amount of yohimibine is most preferably approximately 12 mg to 18 mg per day (paragraphs 0174, 0210, 0260). It is disclosed that the

composition may optionally and additionally contain alkaloids (paragraph 0262). It is disclosed that combining an alpha-1 agonist with forskolin helps to increase thyroid production that is useful in increasing weight loss (Paragraph 0093).

Lawn et al. disclose methods for increasing cholesterol efflux from cells of a mammal by administering forskolin which increases synthesis of cAMP and vinpocetine which inhibits the degradation of cAMP (Column 9, lines 1-16).

Brink discloses a composition for weight control containing about 75 mg of guggulsterones (column 5, lines 47-68, column 6, lines 1-3). It is disclose that the composition can be used to control weight, reduce blood serum lipid and cholesterol levels and increase energy and vigor (Column 5, lines 47-54). The term "vigor" means active bodily or mental strength or force and intensity of action or effect (Column 5, lines 36-40).

Majeed et al. disclose that lean body mass is important for any weight loss strategy and that increased lean body mass regulates body metabolism and helps in losing weight and that the ideal weight management approach should be to reduce body weight in acceptable levels by restoring the optimal proportions of fat to lean body mass (for example skeletal muscles) (Column 1, lines 40-68, Column 2, lines 1-28). It is disclosed that stimulating the enzyme adeynlate cylase thereby increasing cAMP increases the lean body mass and the increase in cAMP in tissues corresponds wells to enhancing the thermogenic response to food (Column 3, lines 35-54). It is disclosed that forskohlin in a daily dose of about 10 to 60 mg which can be divided into a plurality of individual doses is effective in increasing adenylate cyclase, incrasing cAMP levels and ultimately increasing lean body mass (Column 3, lines 55-68, Column 4, lines 1-36). It is disclosed that forskohlin can be administered orally and in combination with other

ingredients, for example black pepper extract containing piperine (Column 4, lines 37-49). It is disclosed that cAMP stimulates the activation of lipase, which stimulates the release of fatty acid from body adipose depots, which released fatty acids stimulate the uncoupling process in the mitochondria, resulting in thermogenesis and provision of fuel to increase thermogenesis (Column 3, lines 60-68, Column 4, lines 1-3).

Marev disclose that vinpocetine increased sera concentrations of glucose and fatty acids and endurance of animals treated with vinpocetine to physical loadings, in this case, swimming was greater (Abstract).

The prior art discloses the combination of caffeine (which increases cAMP), at least one of synephrine (which increases cAMP), hordenine, octopamine, tyramine and N-methyltyramine, yohimbine (which increases cAMP), which promotes weight loss in mammals. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of forskolin, guggulsterone and vinca alkaloid with Caffeine, Adrenergic amine and alpha 2-receptor antagonist. However, the prior art amply suggests the same as the prior art discloses that the caffeine, adrenergic amines, forskolin, guggulsterone and alpha-2-receptor antagonists are used to control weight, that caffeine, adrenergic amines and alpha-2-receptor antagonists increase cAMP and that vinpocetine inhibits cAMP degradation. As such, it would have been well within the skill of and one ordinary skill in the art to combine the above with the expectation that the addition of vinpocetine would potentiate the effects of the caffeine, adrenergic amines and alph-2-receptor antagonists by inhibiting the degradation of cAMP and that the combination of the six components would be effective in controlling weight. Further, it

would have been well within the skill to additionally add Black Pepper extract containing piperine with the combination would also be effective in promoting weight loss.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

The Applicant argues that Vinca Alkaloids and Forskolin are not known as compounds useful for weight control in a mammal and that effects on cAMP do not suggest that the same would be effect in controlling weight. However, as indicated above Forskolin is disclosed in the art to be effective in weight control and enhancing the thermogenic effect to food and that the same is due to its effects on increasing cAMP. Similarly, since vinpocetine is known to inhibit cAMP degradation, one of ordinary skill in the art would expect that vinpocetine would also be effective in weight control by helping to maintain the increased levels of cAMP. As indicated in *KSR v. Teleflex*, one of ordinary skill in the art is not an automaton and is able to think critically. As such, the Examiner's reasoning is not in error and is based on the teachings and suggested of the prior art and not the Applicant's Specification.

The Applicant argues that Claims 38 and 39 do not require an adrenergic amine and that retention of an element's function is an indicia of unobviousness. However, the Applicant fails to indicate what function is retained. Notwithstanding the same, it would be evident to one of ordinary skill in the art, as evidence by the prior art above, that even without an adrenergic amine the combination of vincepotine with one of the other components or a compound that increases cyclic AMP would be effective in controlling weight for the reasons set forth above. In any case, the claims do not exclude the use of adrenergic amines; as such, there is not even an omission of an element.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
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April 4, 2008

/Johann R. Richter/
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